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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,712

03/17/2004

David Brumbach

2003P04138 US02

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7590

01/12/2006

Alexander J. Burke
Intellectual Property Department 5th Floor
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EXAMINER

BARAN, MARY C

ART UNIT

PAPER NUMBER

2857

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,712

Applicant(s)

BRUMBACH ET AL.

Examiner

Mary Kate B. Baran

Art Unit

2857

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The action is responsive to the Amendment filed on 12 October 2005. Claims 1-25 are pending. Claims 1, 3, 9, 11, 15, 17 and 20-24 have been amended.
2. The amendments filed 12 October 2005 are sufficient to overcome the prior objections to the abstract and claims.

Specification

3. The disclosure is objected to because of the following informalities:
(a) On page 3 line 24, "task" should be – tasks –.
Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 9-11, 13, 14 and 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaeffer et al. (U.S. PG Pub No. US 2002/0107641) (hereinafter Schaeffer).

Referring to claims 1-3, 17 and 20-25, Schaeffer teaches a user interface system for processing information related to laboratory tests and results (see Schaeffer, page 5 [0049]), comprising: a display processor for initiating generation of at least one display image including display elements (see Schaeffer, page 4 [0044]) for, enabling a user to enter data identifying an expected laboratory test result of a patient specimen culture (see Schaeffer, page 4 [0048] and pages 7-8 [0081]), a laboratory test result, at least one further expected laboratory test result, at least one further laboratory test result, and a plurality of validation pre-conditions for validating said first laboratory test (see Schaeffer, page 4 [0044]), and for displaying an alert message to a user indicating a failure condition (see Schaeffer, page 8 [0087] and page 9 [0090]) derived by, comparing said expected laboratory test result with said laboratory test result and identifying a first failure condition in response to said laboratory test result failing to match said expected laboratory test result (see Schaeffer, page 5 [0052]); comparing said at least one further laboratory test result with said at least one further expected laboratory test result failing to match said at least one further expected laboratory test result (see Schaeffer, page 5 [0056]); and determining that at least one of said plurality of validation preconditions are not satisfied (see Schaeffer, page 7 [0074]).

Referring to claims 4 and 18, Schaeffer further teaches that said received user entered data identifying an expected result of said laboratory test comprises at least one of an identifier indicating a culture is resistant to a test compound, an identifier indicating a culture is sensitive to a test compound (see Schaeffer, page 5 [0056]), an identifier indicating a positive test result and an identifier indicating a negative test result (see Schaeffer, page 5 [0055]).

Referring to claim 5, Schaeffer teaches that said received user entered data identifying an expected result of said laboratory test comprises a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture (see Schaeffer, page 5 [0053]).

Referring to claim 7, Schaeffer teaches that said microbes are bacteria (see Schaeffer, page 5 [0053]).

Referring to claims 9 and 10, Schaeffer teaches that said interface processor receives user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test (see Schaeffer, page 4 [0044]); said validation processor compares an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result

(see Schaeffer, page 5 [0059]); and said result processor initiates generation of an alert message to a user indicating a failure condition of said individual test performed at a particular time stage of different time stages (see Schaeffer, page 8 [0087]).

Referring to claim 11, Schaeffer teaches that said result processor initiates generation of an alert message to a user in response to occurrence of said failure condition, prompting a user with a user determined message (see Schaeffer, page 8 [0087]).

Referring to claims 13 and 19, Schaeffer teaches that said result processor initiates generation of an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden (see Schaeffer, page 9 [0090]).

Referring to claim 14, Schaeffer teaches that said result processor initiates storage of a record indicating said failure condition was overridden, in response to said user override command, said record being incorporated in a report identifying override command occurrences (see Schaeffer, page 9 [0090]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. (U.S. PG Pub No. US 2002/0107641) (hereinafter Schaeffer) in view of Peck et al. (U.S. Patent No. 5,789,173) (hereinafter Peck).

Referring to claim 6, Schaeffer teaches all the features of the claimed invention except that said quantity identifier identifies a qualitative range of said quantity of microbes per unit area, including an identifiers indicating few or many.

Peck teaches that said quantity identifier identifies a qualitative range of said quantity of microbes per unit area, including an identifiers indicating few or many (see Peck, column 3 lines 35-46).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify Schaeffer to include the teachings of Peck because identifying a range of microbes within an area would have allowed the skilled artisan to determine the strength of the bacteria or if an antibiotic had an effect on the bacteria in the culture.

Referring to claim 8, Schaeffer teaches all the features of the claimed invention except that said received user entered data identifying an expected result of said laboratory test identifies a count value of number of microbes present per unit area of a culture.

Peck teaches that said received user entered data identifying an expected result of said laboratory test identifies a count value of number of microbes present per unit area of a culture (see Peck, column 3 lines 18-34).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify Schaeffer to include the teachings of Peck because identifying a range of microbes within an area would have allowed the skilled artisan to determine the strength of the bacteria or if an antibiotic had an effect on the bacteria in the culture.

6. Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. (U.S. PG Pub No. US 2002/0107641) (hereinafter Schaeffer) in view of Buechler et al. (U.S. Patent No. 6,830,731) (hereinafter Buechler).

Referring to claim 12, Schaeffer teaches all the features of the claimed invention except that one of said plurality of validation preconditions corresponds to an elapsed time period to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test.

Buechler teaches that one of said plurality of validation preconditions corresponds to an elapsed time period to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test (see Buechler, column 12 lines 32-39).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify Schaeffer to include the teachings of Buechler because waiting

for a period of time prior to comparing test results would have allowed the skilled artisan to ensure that the automated system was comparing the correct sets of data (see Buechler, column 12 lines 32-39).

Referring to claim 15, Schaeffer teaches all the features of the claimed invention except an authorization processor for determining whether a user is authorized to override said failure condition and to inhibit override in response to a determination said user is unauthorized.

Buechler teaches an authorization processor for determining whether a user is authorized to override said failure condition and to inhibit override in response to a determination said user is unauthorized (see Buechler, column 9 lines 11-16).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify Schaeffer to include the teachings of Buechler because only permitting authorized users to access the system would have allowed the skilled artisan to prevent unauthorized users from accessing the system and contaminating the data.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. (U.S. PG Pub No. US 2002/0107641) (hereinafter Schaeffer) in view of Moskoff (U.S. Patent No. 6,753,186).

Referring to claim 16, Schaeffer teaches all the features of the claimed invention except that said result processor initiates generation of an alert message with a plurality of different warning severity message levels.

Moskoff teaches that said result processor initiates generation of an alert message with a plurality of different warning severity message levels (see Moskoff, column 14 line 55 – column 15 line 10).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify Schaeffer to include the teachings of Moskoff because breaking the alarm criterion into severity levels would have allowed the skilled artisan to assess how critical the bacteria growth is, and if any antibiotic added has slowed the bacteria growth.

Response to Arguments

8. Applicant's arguments filed 12 October 2005 have been fully considered but they are not persuasive.

Applicant argues that Schaeffer does not teach, "receiving user entered data identifying a laboratory test result of a patient specimen culture", "receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition" and "a validation processor for employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". However, Applicant's arguments are not well taken. Schaeffer teaches identifying a laboratory test result of a patient specimen culture, an expected result of said laboratory test (see Schaeffer, page 4 [0048] lines 4-15) and data identifying a validation pre-condition (see Schaeffer, pages

7-8 [0081]). This data is collected and placed in a database (see Schaeffer, page 5 [0050] lines 1-4) and may be entered by either a patient or a laboratory (see Schaeffer, page 7 [0071] lines 13-15). Schaeffer further teaches comparing new attributes to those already stored to determine a diagnosis as well as treatment (see Schaeffer, page 8 [0085]). The compared data is further used to evaluate patterns which are used to determine the confidence level of the data (see Schaeffer, page 8 [0086]), in other words, detect errors within the database (see Schaeffer, page 9 [0091] lines 16-23).

Applicant further argues that Schaeffer does not teach, "an alert message to a user indicating said first failure condition". However, Applicant's arguments are not well taken, Schaeffer teaches generating reports to represent the confidence level of the data (see Schaeffer, page 8 [0086]-[0087]), and errors such as additional patient data entered or new resistance to bacteria (see Schaeffer, page 9 [0091]).

Applicant further argues that Schaeffer does not teach addressing a validation system during a culture's testing lifecycle; however, this limitation is not specified in the claims.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

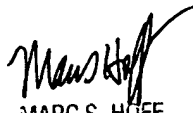
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Kate B. Baran whose telephone number is (571) 272-2211. The examiner can normally be reached on Monday - Friday from 9:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (571) 272-2216. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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SUPERVISORY PATENT EXAMINER
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08 January 2006